UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FEDERAL TRADE COMMISSION, Plaintiff, v. DIRECT MARKETING CONCEPTS, INC., et al, Defendants	CIVIL ACTION NO. 04-CV 11136GAO

AFFIDAVIT OF ANDREW ALDRICH

I, Andrew Aldrich, under oath declare as follows:

1. I am a Massachusetts resident. I attended the University of Rochester where I earned a Bachelor of Science degree in Neuroscience. I also attended the Northeastern University School of continuing education where I earned a certificate in paralegal studies.

2. I have been working with Direct Marketing Concepts, Inc. and ITV Direct, Inc. ("ITV") since April of this year (2005) as a paralegal and science advisor.

3. I have been provided a copy of the "Supplemental Memorandum in Support of Plaintiff Federal Trade Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct Inc., and Donald Barrett and Request for Expedited Treatment" ("Memorandum").

4. Since beginning my employment with ITV, my duties have included gathering and reviewing scientific and related materials that substantiate the claims and statements made in the advertisements produced by ITV. During my review of these materials, I meet regularly with the Company's General Counsel, Michael Sciucco, to discuss the

science and supporting materials that I am reviewing. I also participate in the editing process of the advertisements.

5. I have been involved with gathering and reviewing supporting material for claims made in the Flex Protex advertisement. I reviewed and collected over 200 clinical and scientific studies in support of the claims made in the infomercial (See Exhibit A). Many of the studies meet the "gold standard" of well controlled double blind clinical trials on the ingredients of the product.

6. I have also worked closely with the scientists at Nutracea, Inc., the developer of the product, Reddy Sastry V. Cherukuri, Ph.D., and Rukmini Cheruvanky Ph.D. Both of these scientists have spent years researching the ingredients in the product, and Nutracea has spent millions of dollars on research and development. In addition to my discussions with the scientists at NutraCea I flew out to California to meet with them, tour their laboratory and review the science.

7. In accordance with FTC regulations, and ITV's own policy, we have compiled a significant amount of "competent and reliable scientific data" to support the claims made in the Flex Protex advertisement. This data includes well controlled double blind clinical trials. I am submitting these materials as Exhibit A to this affidavit.

8. Based on the research I have conducted, my own viewing of the advertisement, and my conversations with the scientists at Nutracea, I concluded that the claims made in the advertisement were substantiated by competent and reliable scientific data and provided ITV with a reasonable basis to make the claims identified by the FTC.

9. In connection with ITV's advertisement for Flex Protex, the FTC has contended that the advertisement is not supported by competent and reliable scientific evidence.

This contention is simply not true and the FTC has provided no evidence whatsoever to support it. By their own admission the FTC has not reviewed any scientific literature, has not contacted any scientists to review the research, or reviewed any of the well controlled double blind studies reviewed by ITV.

10. While a full review of the substantiation for the infomercial is beyond the scope and brevity of this affidavit, I will briefly discuss some of the evidence contained in Exhibit A to assuage any concerns the Court may have regarding substantiation for the claims the FTC alleges are made in the show. The FTC has identified 6 claims in the advertisement that they contend are unsubstantiated. I will address each one below:

" that Flex Protex is a natural COX-2 inhibitor that effectively relieves the pain associated with among other diseases arthritis, rheumatoid arthritis, fibromyalgia and gout."

11. This claim which I will address in separate parts is supported by competent and reliable scientific data referencing both the product and its ingredients (including a number of randomized double blind clinical trials (RCT)) that were in the possession of ITV prior to release of the advertisement in question.

"that Flex Protex is a natural COX-2 inhibitor"

12. Curcumin, an ingredient in Flex Protex, is a naturally occurring chemical that has been verified as a COX-2 inhibitor in numerous studies.[1] [2] Glucosamine, another natural ingredient of Flex Protex, has also been shown to block COX2. [3]

"that effectively relieves the pain associated with arthritis and rheumatoid arthritis"

13. Arthritis remains the central indication for Flex Protex with nearly every ingredient demonstrating some anti-arthritic quality. Glucosamine has been verified as an effective pain reliever in cases of arthritis in over 15 randomized double blind medical trials cumulatively representing nearly 2,000 patients some of whom were monitored for up to 3 years. [4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21] Similarly, Yucca [22] and Curcumin[23] have also proven effective in controlled clinical trials for the management of arthritis. Research from animal studies support that Ashwagahnda may also be helpful with the disorder.[24]

14. In regards to rheumatoid arthritis (RA), the Boswellin and omega-3 fatty acid ingredients of Flex Protex have a proven track record. Boswellin is an Indian herb that has been used for rheumatic disease for centuries. Dr. Robert Etzel reported in a clinical study on over 260 patents have confirmed Boswellin supplementation to be safe and beneficial to those suffering from RA.[25]

15. The risolubles base of Flex Protex is a rich source of omega-3 fatty acid, a supplement with proven efficacy in the management of the condition. Two double blind trials reported by Joel Kremer, PhD, established that the addition of omega-3 to the diet of patients with rheumatoid arthritis helped alleviate many symptoms.[26 27]

16. In addition to all the studies on the ingredients, two reports directly related to Flex Protex establish the product's efficacy toward rheumatic disease. In a recent a double blind study a supplement similar to Flex Protex (containing Boswellin, Curcumin, Ashwagahnda, and Zinc: all ingredients in Flex Protex) was shown to help alleviate arthritis related pain and disability.[28] Finally, an animal study conducted on a majority of

the ingredients in the product itself demonstrated it to have anti-arthritic and anti-inflammatory properties.[29]

"effectively relieves the pain associated with fibromyalgia."

17. The use of COX2 inhibitors such as Flex Protex is indicated for pain management in fibromyalgia. In particular, Curcumin inhibits prostaglandin PE2,[30] which has recently been shown to be a pro-pain mediator in human myalgic muscles.[31] It is also known that blocking the COX enzymes (via salicate) reduces post-operative pain in myalgic tissue.[32]

"effectively relieves the pain associated with gout."

18. Like fibromyalgia, the symptoms of gout can be managed by downregulating the COX2 enzyme. [33] [34] [35] Therefore, ITV would have a reasonable basis to make the above claim particularly because the Curcumin ingredient in Flex Protex would offer benefit to the disability. A greater benefit may be derived from the combined action of Curcumin and Boswellin together. Both of these herbs have been demonstrated to potently inhibit the formation of LTB4 [36], a central mediator of pain in gout. [37] [38] It has even been suggested that colchicine (leading medication for gout) acts by inhibiting LTB4. [39]

"that it enables the body to regenerate cartilage"

19. Glucosamine's ability to regenerate cartilage is now firmly established. To begin, glucosamine is a basic building block of cartilage proteoglycans (PGs). All PGs contain glucosamine and it would be impossible for the body to generate any cartilage without utilizing the glucosamine residue.[40] It has also been shown that chrondrocytes, the cells

that secrete cartilage, up-regulate this secretion in response to glucosamine. [41] Animal studies have confirmed that glucosamine regenerates cartilage in a wide range of species including rats, [42] and rabbits. [43]

20. Clinical studies conducted on humans confirm the ability of glucosamine, to regenerate cartilage. In a double blind study conducted by Dr. Drovanti., a comparison of electron microscope images of patient joint cartilage before and after treatment with glucosamine led the researchers to conclude glucosamine "appears to have rebuilt the articular cartilage."[44]

" that not only does Flex Protex not have the health risks associated with other COX2 inhibitors such as Vioxx, but it actually improves cardiovascular health".

21. I have not found any indications that Flex Protex would have such deleterious side affects as Vioxx which has caused the premature deaths of thousands of people.

22. In regards to cardiovascular disease, the ingredients of Flex Protex help to maintain good health in two ways. First, both the risolubles and the Yucca ingredients are proven cholesterol lowering agents (cholesterol is a major source of cardiovascular disease). A double blind study conducted on the risolubles base of Flex Protex itself demonstrated it to be capable of lowering cholesterol.[45] This was also verified in a non published study conducted at the University of New Mexico.[46] Similarly, Robert Bingham and colleagues have verified in a double blind study that supplementation with Yucca lowers cholesterol.[47]

23. Second, Ashwagahnda, a natural ingredient of Flex Protex, has been demonstrated to significantly reduce myocardial injury in mammals. [48]

24. The base ingredient in Flex Protex is rich in phytosterols which the FDA has recognized as a cholesterol lowering ingredient and may reduce the risk of heart disease.

"that it prevents arthritis"

25. Although, this claim is not directly put forth in the advertisement, the development of arthritis is manifestly noted in the narrowing of the space between two bones due to a loss of cartilage. As the disease progresses the joint space gets narrower and narrower. The bones start to grind together leading to pain, swelling, and reduced range of motion. It has been established Nitric Oxide (NO) is key to this progression in that it both stimulates metalloproteinase, enzymes that break down connective tissue,[49] [50] and simultaneously suppresses cartilage growth and may even lead to chrondrocyte cell death. [51] Recent work from Dr. Stefania Marzoco at the University of Salerno established that Yucca extracts inhibits NO synthesase, the enzyme which synthesizes NO.

26. In Flex Protex this effect is bolstered by the increase in cartilage production from the glucoamine, which in and of itself has been identified as an agent capable of inhibiting the furtherance of arthritis. In two large double blind studies it was found that arthritic subjects taking Glucosamine over 3 years experienced no or very little change in measured joint space as compared to arthritic controls. [52] [53]

"that clinical studies prove the product's efficacy in reversing cardiovascular disease and rebuilding cartilage"

27. Clearly all of the above demonstrates that the claims that the product would have benefit toward rebuilding cartilage and cardiovascular health are supported competent and reliable scientific evidence.

"it is good for people of any age, including children"

28. This is true for all of the ingredients:

A) risolubles: No reported allergies or adverse reactions.

B) Glucosamine: The N-acetyl form used here has no reported adverse reactions. Toxicity studies have found it to be as safe as table salt.[54]

C) Ashwagahnda: In a recent report in "Alternative Medicaine Review" Dr. Lakshmi-Chandra Mishra MD states "studies have found various constituents of ashwagahnda exhibit a variety of therapeutic affects with little or no associated toxicity."

D) Boswellin: Boswellin is placed in the highest class of safety by the American Herbal Products Association.[55]

E) Curcumin: In a recent report from the eminent journal *Science*, Mary Egan PhD reports "Human studies indicate that Curcumin is tolerated in extremely large doses without apparent toxicity."[56]

F) Ginger and MSM: There are no reports of adverse reactions to these chemicals at in the amounts in the product.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 28th day of September, 2005 in Beverly, Massachusetts.

ANDREW ALDRICH

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